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EXAMINER	
JOHNSON, N	
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DATE MAILED:

03/27/00

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

## ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

- a) ☐ is extended to run \_\_\_\_\_ or continues to run \_\_\_\_\_ from the date of the final rejection
- b) ☒ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.135(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Appellant's response to the final rejection, filed 2/16/00 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:
- ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
  - ☐ They raise new issues that would require further consideration and/or search. (See Note).
  - ☐ They raise the issue of new matter. (See Note).
  - ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
  - ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE:

2. ☐ Newly proposed or amended claims \_\_\_\_\_ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.
3. ☒ Upon the filing an appeal, the proposed amendment ☐ will be entered ☒ will not be entered and the status of the claims will be as follows:

Claims allowed: \_\_\_\_\_

Claims objected to: \_\_\_\_\_

Claims rejected: 1-3

However;

☐ Applicant's response has overcome the following rejection(s): \_\_\_\_\_

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because see attached

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

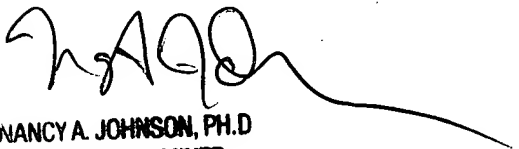
NANCY A. JOHNSON, PH.D.  
PRIMARY EXAMINER

### ADVISORY ACTION

1. The rejection of claims 29-31 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained. The recitation an immunogenic peptide "consisting essentially of" 5-20 contiguous amino acids remains vague and indefinite. The applicant notes that the Federal Circuit has taken the following "view of the use of the phrase 'consisting of' in a chemical claim ...Its use leaves the claim open for the inclusion of unspecified ingredients which do not materially affect the basic and novel characteristics of the **composition**" (emphasis added). It is noted that the claim is drawn to a "composition comprising .... an immunogenic peptide consisting essentially of 5-20 contiguous amino acids." Thus, the use of the recitation "consisting essentially of" is language to be applied to the "immunogenic peptide" recited in the claim and not to the overall "composition." It remains the case that the nature of substitutions to the recited chemical structure of the immunogenic peptide encompassed by the recitation "consisting essentially of" is unclear. The applicant argues that it is well recognized in patent law that 'consisting essentially of' is not equivalent to 'comprising,' but is partially closed language, which restricts the inclusion of unspecified ingredients to those that do not materially affect the basic and novel characteristics of the claim. In the instant claim it is unclear what "basic and novel characteristic" define the claimed peptides. On one hand, doesn't the actual amino acid sequence of a peptide provide a very basic definition of its character? In this case, adding even a single additional amino acid to the peptide would change its basic characteristics. Or is it the case that the novel and basic characteristic of the claimed peptide is that it is "immunogenic"? In this case, adding additional amino acids to a peptide does not detract from its immunogenicity. The applicant argues that the phrase "consisting essentially of" has a well-recognized meaning within the chemical and biochemical art and its use distinguishes the claimed product over prior art having at least one additional component." This is not found persuasive. It is unclear what constitutes the "additional components." If the additional components are interpreted to be additional amino acid residues, how does "consisting essentially of" differ from the totally closed language 'consisting of' as applied to peptide products? Further, the applicant argues that a simple search of the

USPTO web site of "protein" and "consisting essentially" in the claims yielded over 1100 such issued US patents. This is not persuasive, the occurrence of these two terms in the same claim is not relevant.

2. The rejection of claims 29-31 under 35 U.S.C. 102(b) as being anticipated by WO 92/21767 is maintained. The applicant argues that the "cited reference describes a peptide containing more than 5-20 amino acids. The claims use partially closed language, which necessarily excludes fragments of the gp100 molecule disclosed in the cited reference." This is not found persuasive. The claim is drawn to immunogenic peptides consisting essentially of 5-20 contiguous amino acids of the gp100 protein. The cited art discloses an immunogenic peptide of 29 amino acid residues of the gp100 protein. The applicant has noted that it is well recognized in patent law that 'consisting essentially of' is partially closed language, which restricts the inclusion of unspecified ingredients to those that do not materially affect the basic and novel characteristics of the claim. In the instant case, the additional amino acid residues of the art disclosed peptide do not materially alter the basic property of the claimed peptide, that it is "immunogenic." Thus, the cited art discloses compositions and methods that are the same as that claimed.

  
NANCY A. JOHNSON, PH.D  
PRIMARY EXAMINER

March 21, 2000